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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/591,177	06/09/2000	Adrien R. Beaudoin	850865.90015	3512

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EXAMINER
SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
1634	12

DATE MAILED: 06/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/591,177	Applicant(s) BEAUDOIN ET AL.	
	Examiner Bradley L. Sisson	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *15-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-14, with the election of thioether and alkyl group as the substituent and group "X" in Paper No. 11 is acknowledged. The traversal is on the ground(s) that the events set forth in Groups II, III, and IV are related in that they set forth a chain of events stemming from exposing an NTPDase to a compound of Group I. This is not found persuasive because the various methods are considered to be drawn to different methods that are comprised of different method steps and which can result in different end products. It is noted with particularity that the method of claim 15 is to result in the modulation of activity of an NTPDase while the method of claim 17 does not require any modulation of activity of a NTPDase but is to modulate the level of any purine, purine derivative or purine metabolite in any biological system by any means. For purposes of examination, the aspect of just what constitutes a "purine metabolite" and a "purine derivative" is considered to encompass virtually any molecule that comprises carbon and/or nitrogen and does not have to come directly from a process whereby purine is metabolized or derivatized but only that the molecule could come from the metabolism or derivatization of any purine.

2. Argument is also advanced at page 7 of the response of 23 April 2002 in that the restriction requirement was not placed against the claims in the first Office action. Applicant directs attention to 37 CFR 1.146. While agreement is reached in that it is preferable that a restriction and election of species requirement be placed against the claims at the time of first action by the Office, MPEP 811, citing 37 CFR 1.142(a), clearly states that such a requirement

can be made at any time before final Office action. For convenience, the second sentence of 37 CFR 1.142(a) is reproduced below:

37 CFR 1.142(a) , second sentence states: "[i]f the distinctness and independence of the invention be clear, such requirement will be made before any action upon the merits; however, it may be made at any time before final action in the case at the discretion of the examiner." This means the examiner should make a proper requirement as early as possible in the prosecution, in the first action if possible, otherwise, as soon as the need for a proper requirement develops.
Before making a restriction requirement after the first action on the merits, the examiner will consider whether there will be a serious burden if restriction is not required.

For the above reasons, and in the absence of convincing evidence to the contrary, the requirement is still deemed proper and is therefore made FINAL.

3. Claims 15-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

Claim Objections

4. Claims 1-14 are objected to because of the following informalities: The claims read on non-elected embodiments. Appropriate correction is required.

Specification

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. It is noted with particularity that the elected claims are not drawn to any method of using the C8-substituted purine nucleotide analogs.

6. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As presently worded, and as elected by applicant pursuant to the restriction and election of species, claims 1-14 have been read as encompassing virtually any C8-substituted purine analog that comprises at the C8 position a thioether bound directly to an alkyl group. Purines are considered to encompass both ATP and GTP. A review of the specification finds that 7 different compounds have been synthesized, of these 7, 4 are based on adenosine and three are based on adenosine 5'-triphosphate. The compounds are:

a. 8-(Thiocycloheptyl)adenosine;

b. 8-(Thio-2,2-dimethyl-propyl)-adenosine;

c. 8-(Thioethyl)-adenosine;

d. 8-(Thio-n-hexyl)adenosine;

e. 8-(Thiocycloheptyl)-adenosine 5'-triphosphate;

f. 8-(Thio-2,2-dimethyl-propyl)adenosine 5'-triphosphate; and

g. 8-(Thioethyl)-adenosine 5'-triphosphate.

As seen above, the seven molecules described in the subject application comprise a common base, adenosine. The specification has not been found to describe any molecule where guanine is a component. Accordingly, the specification does not reasonably suggest that applicant was in possession of any C8-substituted guanine analog.

9. As elected by applicant, the claims have been examined only to the extent that they read on the elected species and the specification has been reviewed in kind. To that end, the elected species encompasses any and all alkyl groups, yet a review of the seven finds but four alkyl moieties being used: dimethyl-propyl, ethyl, hexal and cycloheptyl. Clearly, the aspect of the claims encompassing any and all possible alkyl moieties speak to a very broad genus of compounds, compounds that the specification des not reasonably suggest that applicant was in possession of at the time of filing. Rather than set forth a representative number of molecules that would reasonably suggest that applicant was in possession of the complete genus of molecules, applicant is seemingly trusting in the claimed invention being obvious to those of skill in the art at the time of filing. Such an argument, however, is not dispositive of the specification needing to satisfy the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir.

1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

In view of such limited disclosure, and in the absence of convincing evidence to the contrary, the specification has not been found to satisfy the written description requirement as set forth under 35 USC 112, first paragraph.

10. Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not disclose in such full and complete detail how the genus of compounds is to be made and used. As presently worded, claims 1-14 encompass a wide genus of biochemicals, some of which may have a useful activity. The specification does not set forth a reproducible method by which those useful compounds are readily determined, nor does the specification disclose what specific utility these compounds have and then disclose a method by which they can be used. The specification has been found to set forth in sufficient detail how some seven molecules are to be made (pages 17-21). A review of the disclosure finds that in Example 2, "Enzymology of purine nucleotide analogs," the method employed requires reagents that are not publicly available; see page 21, bridging to page 22, where "[Sar^9, Met $(O_2)^{11}$]SP (NK-1) was synthesized by Dr. W. Neugebauer from the Universitė de Sherbrooke."

None of the examples provided in the specification set forth how any other C8-substituted purine, especially those comprising a guanine, or any other alkyl group, are to be used. As set forth above, the specification does not reasonably suggest that applicant was in possession of the genus of compounds for which patent protection is currently being sought. It is well settled that one cannot enable the use of a product that they do not yet possess. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

> " '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').
>
> *****
>
> "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. <u>However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art.</u> It is the

> specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

Accordingly, and in the absence of convincing evidence to the contrary, the specification has not been found to teach in sufficient detail how to make and use the full genus of compounds being claimed.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

12. Claims 1-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Erion et al. (US Patent 6,312,662 B1).

13. Erion et al., columns 85-87, disclose C8-substituted purine analogs. In column 87 the development and use of C8-substituted analogs where the substitution is an 8-thioalkyl is explicitly taught. Such a teaching is considered to meet the limitations of claims 1-14.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

16. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

B. L. Sisson

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
June 18, 2002